UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/801,443	03/07/01	GUPTA S	ARC 2863 N1

HM12/0911

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EXAMINER	
TRAN,S	
ART UNIT	**PAPER NUMBER**
1615	2

DATE MAILED: 09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/801,443	Applicant(s) Gupta et al.
	Examiner Susan Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed 03/07/01.

Claim Objections

1. Claim 5 is objected to because of the following informalities:

In claim 5, the phrase "an pharmaceutically" should read "and pharmaceutically".

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 7, 8, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the use of the phase "acceptable salt", the language is confusing. It is suggested to amend to "acceptable salt thereof".

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Use claims are not considered to be on of the permitted classes of invention. Applicants should recite a method or process that includes at least one step.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Baichwal US 5,399,359 .

Baichwal discloses sustained release formulation comprising from about 5 mg to about 20 mg oxybutynin and its pharmaceutically acceptable salts thereof (column 2, lines 60 through column 3, lines 1-8).

5. Claims 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Aberg et al. US 5,532,278.

Aberg teaches a method for treating urinary incontinence while avoiding and reducing adverse effects, e.g. xerostomia (dry mouth), using from about 0.25 mg to about 100 mg of oxybutynin (column 1, lines 65 through column 3, lines 1-36). The reference's oxybutynin is a controlled release oral dosage form that is administered daily (id). The rate of release of up to 24 hours is clearly inherent since oxybutynin is used in the same form, e.g., controlled release dosage for daily use for the same purpose, e.g., to treat urinary incontinence while avoiding and reducing adverse effects, e.g. xerostomia (dry mouth).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal.

Baichwal is relied upon for the reasons stated above, the cited reference is silent as to the rate of oxybutynin release per hour. However, it would have been obvious for one of the ordinary skill in this art to, by routine experimentation determine suitable rate of release of oxybutynin, because the cited reference teaches the advantageous results in the use of oxybutynin and its pharmaceutically acceptable salts thereof in a controlled release dosage form. Further, it

is the position of the examiner that no criticality is seen in the particular rate of release since the prior art obtains the results desired by applicants, i.e. a sustained release formulation comprising oxybutynin and its pharmaceutically acceptable salts thereof. The particular rate of release has not been shown to provide any unusual and/or unexpected results over the applied reference. Applicants' attention is called to column 2, lines 38-44, where the prior art teaches that the oxybutynin is being released at a controlled rate such that therapeutically beneficial blood levels of the medicament are maintained over an extended period of time, i.e. providing a 24 hour dosage form.

6. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aberg et al., in view of Baichwal.

Aberg teaches a method for treating urinary incontinence and reducing xerostomia or dry mouth using oxybutynin and its pharmaceutically acceptable salts thereof (column 2, lines 1-10). The formulation comprising from about 1 mg to about 100 mg in a single dose of oxybutynin and its pharmaceutically acceptable salts thereof, further comprising carriers (column 3, lines 13 through column 4, lines 1-10). The formulation can be administered by controlled release means (column 4, lines 20-26).

Aberg is silent as to the teaching of the controlled release over 24 hours.

Baichwal in column 2, lines 38-44, teaches that the oxybutynin is being released at a controlled rate over an extended period of time, i.e. providing a 24 hours dosage form.

The examiner notes that cited references fail to teach the specific rate release per hour of oxybutynin. However, it would have been obvious for one of the ordinary skill in the art to, by routine experimentation determine suitable amount of carrier to achieve the desire rate of release of oxybutynin. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to use Aberg's formulation with the controlled release in view of the teaching of Baichwal. The reason for this modification is to obtain a sustained release formulation of oxybutynin that can provide controlled release up to 24 hours, and also to lessen the adverse effects.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Theeuwes et al., and Callaway are cited as being of interest for the teaching of oxybutynin in a controlled release dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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